

EXHIBIT 1



MATERIAL DATA SAFETY SHEET TALC

Plaintiff's Exhibit
No.

P-37

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Section 1. Product and Company Identification					
Product Names					
Grade 25 USP		Imperial 180 USP		Imperial 200 USP	
Imperial 250 USP		Imperial 400 USP		Imperial 400Y USP	
Imperial 500 USP		Imperial 1885L USP/BC		Imperial 1889L USP/BP/EP/BC	
Imperial 1890 USP/BC		Imperial 1892L USP/BP/EP/BC		Olympic H USP	
Suprafino HP USP		Supra H USP		Olympic HY USP	
Supreme H USP					
Synonyms Talcum powder, Soapstone, Steatite					
Chemical Name	Talc ; Hydrous magnesium silicate	CAS#	14807-96-6	Chemical Family	Phyllosilicates
Manufacturer	Luzenac America, Inc.		Emergency Health		
	8051 E. Maplewood Avenue, Bldg 4		Information (24 hrs)		
	Greenwood Village, CO 80111		303-623-5716		
	Toll-free +1-800-325-0299 (General Information)				

Section 2. Composition/Information on Ingredients			
Substance	CAS#	% by Weight	TLV - TWA
Talc	14807-96-6	98-100	2 mg/m3 respirable fraction (ACGIH)
Dolomite	16389-88-1	0-2	Use Talc TLV for total exposure measurements

Section 3. Health Hazards Identification and Emergency Overview	
Emergency Overview	Under normal conditions of use, this product is not expected to create any unusual emergency hazards. This product is NOT flammable, NOT reactive, NOT explosive, has NO flash point, and poses NO special hazards in the presence of fire.
<p>Potential Health Effects from Acute and Chronic Occupational Exposures to Talc</p> <p>TARGET ORGANS</p> <div style="text-align: center;"> </div> <p>LUNGS, RESPIRATORY SYSTEM</p>	
Inhalation	<p>ACUTE: Exposure to a large concentration of air-born dust of this material may cause mechanical irritation of the mucous membranes and respiratory tract.</p> <p>CHRONIC: Repeated or prolonged inhalation of air-born dust of this material may cause scarring of the lungs (pulmonary fibrosis), with shortness of breath, chronic cough, and respiratory assisted heart failure. Prolonged exposure to talc can produce symptomatic talc pneumoconiosis (talcosis).</p>
Skin Contact	<p>ACUTE: Direct contact may cause dryness, or may cause mild irritation if an allergic predisposition exists.</p> <p>CHRONIC: Prolonged contact may cause dryness of the skin, or may cause mild irritation if an allergic pre-disposition exists</p>
Eye Contact	<p>ACUTE: Direct contact with dust may cause mechanical irritation of the eyes.</p> <p>CHRONIC: Repeated exposure may cause conjunctivae inflammation.</p>
Ingestion	<p>ACUTE: This material is considered to be harmless and inert when ingested.</p> <p>CHRONIC: Repeated ingestion of large doses of talc for 13 and 10 successive days by rabbits and mice revealed negative teratogenic and carcinogenic results.</p>



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Section 4. First Aid Measures	
Inhalation	Remove from exposure area to fresh air. If breathing has stopped, perform artificial respiration and get medical attention immediately. Keep person warm and at rest. Treat symptomatically and supportively.
Skin Contact	Apply common skin moisturizers to relieve dryness. Irritations are uncommon; however, if irritation or redness develops, seek medical attention. Broken skin can be cleansed with mild soap and water.
Eye Contact	Wash eyes with large amounts of water or normal saline solution. If irritation or redness develops, seek medical attention.

Section 5. Fire Fighting Measures	
Flammability	This product is NOT flammable, NOT reactive, NOT explosive, has NO flash point, and poses NO special hazards in the presence of fire. Firefighters require NO special protective equipment or precautions.

Section 6. Accidental Release Measures	
Small Spill	Use vacuum to clean up spillage. Place in sealed container.
Large Spill	For large spills, shovel or sweep up (while keeping dispersion of dust in air to a minimum) and place into suitable sealed containers for reclamation or later disposal. Residue should be cleaned up using a high-efficiency particulate filter vacuum. The use of water wash-down is not recommended. Wet material can cause a surface used for walking to become extremely slippery. Talc is not considered a hazardous waste by RCRA criteria (40 CFR 261).

Section 7. Handling and Storage	
Handling & Storage	Handle in ways to minimize the creation of dust. Preserve product in sealed containers.

Section 8. Exposure Controls & Personal Protection	
Personal Protection	Use NIOSH approved dust respirator. Use safety glasses or dust tight goggles. No special skin protection is usually required, but gloves should be worn by workers susceptible to skin irritation.
  	
Controls	Provide local exhaust or process enclosure ventilation to meet published exposure limits (TLV).

Section 9. Physical & Chemical Properties	
Appearance	White to grayish-white powder
Odor	Slight earthy odor.
Flammability	This product is NOT flammable, NOT reactive, NOT explosive, has NO flash point.
Specific Gravity	2.8 (water = 1.0)
Melting Point	None



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pH	Slightly basic (10% slurry in water)		
Solubility	Water: <1 mg/mL @ 21 C	Acetone : <1 mg/mL @ 21 C	Alkalies: Insoluble
	Ethanol: <1 mg/mL @ 21 C	Cold acids: Insoluble	

Section 10. Stability & Reactivity Data	
Stability	This product is stable, non-reactive, and non-corrosive.
Incompatibility with various substances	Non reactive/none known.

Section 11. Toxicological Information	
Toxicology	<p>NIOSH Registry Number: WW2710000 SAX Toxicity Evaluation: THR: Not available Carcinogenic Status: IARC: (2006 in preparation) Has concluded that perineal use of talc-based body powder is possibly carcinogenic to humans (Group 2B). This is not a route of exposure relevant for workers and applies to one specific use of talc only. IARC: (2006 in preparation) Inhaled talc not containing asbestos or asbestiform fibres not classifiable as a human carcinogen (Group 3) OSHA: Not listed. ACGIH: A4 – Not Classifiable as a Human Carcinogen NTP: Not listed. A 2-year inhalation study demonstrated clear evidence of carcinogenic activity in female rats at exposure levels of 18 mg/m³. Some evidence of carcinogenic activity was observed in male rats at the same level. No evidence of carcinogenic activity was found in mice (NTP TR-421). Tumorigenic Data: TCLo: ihl-rat 11 mg/m³/1Y-I TDLo: imp-rat 200 mg/kg Other Toxicity Data: Skin and Eye Irritation Data: skn-hmn 300 ug/3D-I MLD Teratogenicity (Reproductive Effects Data): Not available. Mutation Data: Not available.</p>

Section 12. Ecological Information	
Ecological Data	
Species	Alga (<i>Selenastrum capricornutum</i>) <i>Daphnia Magna</i> <i>Daphnia Magna</i>
Test	Acute
Endpoint	Growth inhibition immobilization Reproduction
	Growth rate 48hr-EC50 21 day-EC50 21 day-NOEC
	48hr-EC50 48hr-NOEC 48hr-EC50 48hr-NOEC
Conc. (mg/L)	
FY	
References	

*AUG=Area Under Growth curve

Section 13. Disposal Considerations



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Waste Disposal Information Talc is not considered a hazardous waste by RCRA criteria (40 CFR 261). Dry material can usually be land-filled. State and Local regulations/restrictions are complex and may differ from Federal regulations. Responsibility for proper waste disposal is with the owner of the waste.

Section 14. Transport Information

Transport Information U.S. Department of Transportation - DOT: No classification assigned
CANADIAN Transportation of Dangerous Goods: No classification assigned
LAND Transport - ADR/RID: No classification assigned
AIR Transport - IATA/ICAO: No classification assigned (International Air Transport Association/International Civil Aviation Organization)
MARITIME Transport - IMDG: No classifications assigned International Maritime Dangerous Goods)
HARMONIZED Tariff Code: Talc – crushed or powdered. 2526.20.00. (Stat. Suffix 00)
EPA TSCA 12(B) Export Notification: Not listed

Section 15. Regulatory Information

Chemical Inventories EPA TSCA Status: Listed (CAS # 14807-96-6) EINECS (European No: 238-877-9)
CEPA Domestic Substance List – DSL: Listed CEPA Non-domestic substance List – NDSL: Not listed
AICS (Australian – NICNAS) ECL (Korean No: KE-32773)
SWISS (Giftliste No: G-6939) PICCS (Philippines)
ENCS/MITI (Japan) – Talc exempt IECSC (China): Listed

Other Pertinent Classifications/Regulations

CALIFORNIA PROP 65 Status: Talc not listed
STATE RIGHT-TO-KNOW: Talc listed – Illinois; Massachusetts; New Jersey; Pennsylvania; Florida
CLEAN AIR ACT – Ozone Depleting Chemicals (ODC's): None
CONEG Approved Packaging: Yes
NFPA RATINGS: (Scale 0-4) Health = 1, Fire = 0, Reactivity = 0

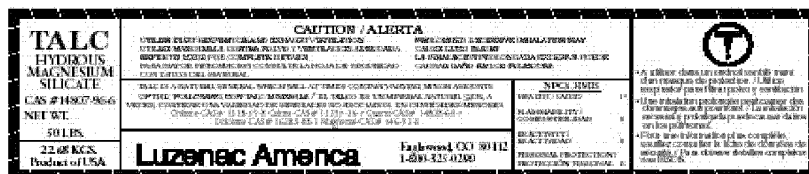
NPCA: National Paint and Coatings Association – Hazardous Material Identification System (HMIS)

HEALTH: 1* (Chronic Potential)
FLAMMABILITY: 0
PHYSICAL: 0
PERSONAL PROTECTION: dust respirator, glasses or goggles, gloves

Section 16. Other Information

Label Hazard Warning CAUTION - PROLONGED EXCESSIVE INHALATION MAY CAUSE LUNG INJURY

Label Precautions UTILIZE DUST RESPIRATOR AND EXHAUST VENTILATION. REFER TO MSDS FOR COMPLETE DETAILS



TYPICAL APPEARANCE OF PRODUCT LABEL



MATERIAL DATA SAFETY SHEET TALC

**Primary
References
for Key Data**

ACGIH - Documentation of TLV's 2001
 OSHA - Chemical Sampling Information: Talc (Containing no asbestos) (Revised 1/15/1999)
 OSHA - TALC (Containing no asbestos). OSHA comments from the June 19, 1988 Final Rule on Air Contaminants Project extracted from 54FR2324 *et. seq.*
 OSHA - Compliance Interpretation Letter dated August 22, 2000 regarding talc products containing less than 1% quartz.
 OSHA - Guidelines for Employer Compliance (Advisory) 1910.1200 App E
 NIOSH - Pocket Guide to Chemical Hazards. Talc (containing no asbestos and less than 1% quartz).
 NIOSH - REL's and General Recommendations for Safety and Health. [TALC (containing no asbestos).
 AIHA - Hygienic Guides Series – Talc (1982)
 IARC - Talc Vol.: 42 (1987) (p.185) 5. Summary of Data Reported and Evaluation; Supplement 7: (1987) (p.349) Talc Not Containing Asbestiform Fibers (Group 3).
 CCOHS – Database MSDS FTSS. Network Version 2002.
 NTP – RoC/NIEHS Database. Network Version 2002.

Glossary

ACGIH – American Conference of Governmental Industrial Hygienists
 AIHA – American Industrial Hygiene Association
 CCOHS – Canadian Centre for Occupational Health and Safety
 IARC – International Agency for Research on Cancer
 NIOSH – National Institute of Occupational Safety and Health
 NTP – National Toxicological Program
 OSHA – Occupational Safety and Health Association
 PEL – Permissible Exposure Level
 TLV – Threshold Limit Value
 TWA – Time Weighted Average

**Important
Notice**

Luzenac America, Inc. provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose.

Issued by

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EXHIBIT 2

JOHNSON'S® Baby Powder | Johnsons Baby

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Johnson's

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JOHNSON'S® Baby Powder

Keeps skin feeling soft, fresh and comfortable



It's a classic. JOHNSON'S® Baby Powder helps to eliminate friction while keeping skin cool and comfortable. It's made of millions of tiny slippery plates that glide over each other to help reduce the irritation caused by friction.

- Helps eliminate friction
- Clinically proven to be safe, gentle and mild
- Allergy and dermatologist-tested
- Clean, classic scent

For skin that feels soft, fresh and comfortable, apply JOHNSON'S® Baby Powder close to the body, away from the face. Shake powder into your hand and smooth onto skin.

Ingredients

Talc, Fragrance

When to Use

Use anytime you want skin to feel soft, fresh and comfortable. For baby, use after every bath and diaper change.

Safety

For external use only. Keep out of reach of children. Close tightly after use. Do not use on broken skin. Avoid contact with eyes. Keep powder away from child's face to avoid inhalation, which can cause breathing problems.

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No.

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SHOWER to SHOWER® Absorbent Body Powder

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to SHOWER®

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The Power of Powder

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Just a sprinkle a day
helps keep odor away
Have you had your sprinkle today?

BUY NOW



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The Power of Powder



A sprinkle a day helps keep odor away. And that's not the only benefit of SHOWER to SHOWER®. Here are some more!

- ✦ Your body perspires in more places than just under the arms. Use SHOWER to SHOWER® to feel dry, fresh and comfortable throughout
- ✦ Pamper yourself with a soft touch and light fragrance.
- ✦ No more stained clothes - powder provides invisible wetness protection
- ✦ With powder on, clothes glide on like a breeze and won't cling.

Get active:

Use before (or after) a workout or hitting the dance floor for a just-showered fresh feeling.

Keep shoes smelling fresh:

Just sprinkle a little powder into your shoes, boots, or sneakers to help them fresh and keep your feet dry.

Leave sand at the beach:

Sprinkle powder generously anywhere wet sand is clinging to your skin, then brush the sand away!

Tame your mane:

No time to shower? Use a sprinkle of powder in your hair between washes to tame excess oil and add a hint of fresh fragrance.

Stay cool:

When the heat of summer turns up, a sprinkle of SHOWER to SHOWER® helps cool you down all over!

Feel smooth:

Add powder to your skin after applying lotion to quickly absorb the stickiness.

Soothe your skin:

Sprinkle on problem areas to soothe skin that has been irritated from friction after a bikini wax to help reduce irritation and discomfort.

Relax:

Lightly dust your sleepwear or sheets to make bedtime peaceful and luxurious.

SHOWER to SHOWER®

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JOHNSON'S® Baby Powder

Keeps skin feeling soft, fresh and comfortable

It's a classic. JOHNSON'S® Baby Powder helps to elir friction while keeping skin cool and comfortable. It's m millions of tiny slippery plates that glide over each othe reduce the irritation caused by friction.

- Helps eliminate friction
- Clinically proven to be safe, gentle and mild
- Allergy and dermatologist-tested
- Clean, classic scent

The JOHNSON'S® Difference

For skin that feels soft, fresh and comfortable, apply Johnson's Baby Powder close to the body, away f the skin. Powder into your hand and smooth onto s

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Clinically proven to be pure, mild and gentle

From baby's first hospital bath through every special milestone, moms and healthcare professionals alike trust JOHNSON'S® baby products to provide the "best in care."

Our Products

category

baby's skin
bath time
bedtime
playtime
natural

life stage

newborn
baby
toddler
mother

baby care need

cleanse
moisturize
hair care
diaper care
sun protection
nursing

Our products have stood the test of time.

Whether you're purchasing one of our timeless classics or a newer release, with JOHNSON'S® you're always getting the clinically proven gentle formulas that have made us the most trusted name in baby care for more than 100 years.


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Add a layer of gentle, loving protection

You put your baby's safety first, and so do we. All of our baby products are formulated to cover your baby from top to toe with pure and gentle protection.



Newborn Skin Care

Learn about her delicate skin. Your newborn's skin is a unique and an essential shield that offers protection from the outside world.

[Read more](#)

Skin Science

- Your baby's skin is more susceptible to irritants and to changes in temperature and humidity.
- While your baby's skin is naturally more hydrated than your own, during the first 12 months of life, it also loses water more quickly.
- Your baby's skin requires more protection to keep it clean and moisturized.

See more on the JOHNSON'S® Brand Difference



Basics of Baby Skin



Sun Protection



Benefits of Infant Massage



Preventing Diaper Rash



Your Baby's Changing Skin



Understanding Baby Skin

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EXHIBIT 3

SHOWER to SHOWER® Task Force- BP Brainstorm
July 14, 2004

Challenge #1: Powder Category Decline

- Explore needs states: pregnancy, menopause, "chubbiness", diabetes
- Advertise through mass transit
 - Subway reminders and subway maps
 - Retail tie-in
 - Sampling
 - Coupons on Metro Cards
- Use Duane Reade for PR – on the street or in-store with displays and jingle playing
- Radio ads – geo-targeted, radio personalities?
- Helps runners with chafing
 - Could do promotions around running events (pre-marathon bags)
 - Include in training kits they can buy
- Race for the Cure promotions
- Education to younger consumers

Challenge #2: STS Share Decline

- Education is key. Get people back into a daily powder routine by telling them how valuable our product is.
 - Surround Sound
 - Need to answer: Why use powder?
 - Possibly go beyond current benefits and look at anti-itch and foot care (more like GOLD BOND®)
- "Soup to nuts" account specific program is most effective; surround sound; start over explaining benefits of powder
- Redefine who our targets are (what do we mean by women 35+?)
 - Can look at men, Redacted women, heavy women
- Go beyond JOHNSON'S® Baby Powder and fragrance; they can't do things like Sport or Shimmer
- We have higher standards of talc that Private Label does not
 - Do we have to keep these higher cost standards?
 - Need to make it worth the extra cost
- Account specific programs? Maybe spot TV tied with specific markets
- Make 1 oz. more available for sale
- Vacationers more willing to try new routines/products
 - Possibly target cruises, the beach, camping, outdoors
- Potential in women's sports markets
- Make scent names more current
- Turn powder into daily regimen by partnering with other products such as women's health or even tooth brushes, something everyone sees as being used daily



- Celebrity endorsements: someone professional but would get the idea away from “Grandma’s powder”
 - Limo drivers handing out samples to get celebrities to try it
 - Make Patti LaBelle or Aritha Franklin spokeswomen
 - Send out celebrity mailings to anyone who might get hot while they work. This could also go to anchormen, like Katie Couric for example.
 - Ideally we would get the reaction that Purpose saw when Dr. Phil’s wife mentioned it
 - Could also get beauty personalities to promote it, especially with the new shimmer
- Maybe get product placed in more high-end retailers than just the Mass COT. More attention from places like Bath and Body Works and Ulta.
- Alternative forms of powder and different placements could be key
- On pack attachments for different delivery: powder puffs and brushes
- Could also attach unrelated items for different messages. For example coupons for greeting cards around Mother’s Day promotes family values and relationships.
- Message that it’s time to “grow up to adult powder”
- Direct mailings with powder samples
- In-book sampling
- Fragrance scratch-n-sniff on FSI
- Scratch and sniff labels
- Floor mats to get customers to actually look for Shower at the retailer. Might need to put them in other spots to get younger potential users down the aisle.
 - Could possibly go in personal care if the idea is that you want something to keep you fresh and clean
 - Partner with Carefree, or Catalina (same idea of our product will bring freshness)
 - Would also reinforce how everyday powder should be
- Sampling/tie-in to Weight Watchers
- We know that people usually purchase Shower on their stock up store trips, not just milk and bread runs
- Hang tags on gym bags or sneakers (or coupons) and could also cross merchandise with seasonal wear
- 101 uses: approximately 50 beauty uses? 50 sport uses? Others:
 - Play up seasonality more: use it at the beach to take off the sand
 - Takes squeaks out of hardwood floors (find interesting uses)
- Wal-Mart market basket data (Nancy f/u)
- X merchandising within J&J
 - Viactiv, Tylenol pairing up with Shower because women trust these brands
- Position to menopause specifically: “heat reliever”; “cools hot flashes”; this way lots of PR would follow

- Harris Interactive Study for PR: i.e. what do you want when you're hot? (for example: powder, a fan, a cool drink, etc., to cool you down)
- More interesting packaging, possibly a more unique cylinder shape so that customers are more willing to spend more money
- Work with bowling alleys (put powder in shoes)
- Baseball gloves, swim caps
- Menopause survival kit
 - Advertise as helping with night sweats and hot flashes
- Obesity platform
 - Focus on Redacted women and obesity
 - What makes her comfortable and confident?
- Create loyalty through frequent buyer program
- Try starting a completely unique and account specific program
- Create STS website and make connections with online retailers
- Make dollar stores better opportunity
- Can we improve our claims beyond time released fragrance?

Challenge #3: Aging Users, How Bring New/Younger Users

- NASCAR displays, signage and any brand linkage
 - Did this 1996-1998 and it did well
- Seasonal approach and alternate usages (PR)
- Rally around specific dates/times of the year and relationships
- Sampling at vacation spots
- Try to market the values of a mother/daughter relationship around powder as well as father/son around Sport
- Teens could be a market because they are more concerned with fragrance and freshness than messiness
- Look at the KY model - think about a correlation between Shower and closeness among people
- Maybe look into more of a beauty focus

Redacted

- Atlanta test results?
 - Grass roots efforts effective?
- SMSI: do they market with Anderson? How leverage this org.?
Redacted
- Make writing a new jingle into a competition
 - For example: A&W recent contest or like American Idol where the consumer or radio audience can select the one they like the best, with winner being put in commercial for STS

- Hospitals
 - Could be giveaways to patients, sampling
 - Sell in hospitals – patients would be willing to buy from hospital shop if you can't shower for an extended period of time; chafing/bed sores
 - More comfortable with name brand so willing to pay a little more better than hospital brand
- Get in on the college bus tour? While girls are learning about skincare guys could also be hearing the benefits of Sport powder.
- Better placement, can we get our line placed in baby or foot care?
- Partner with lower end shoe store like Payless to promote powder usage in shoes
- Product Ideas:
 - Invisible powder
 - Tinted powder
 - Tinted hair powder (already in Europe, can Beatrice get for us?)
 - Bronzer powder
 - Talk to Alexandra – learn European trends
 - Liquid powder in tubes (could also lead to different sampling mediums)
- STS conversion:
Redacted
 - General Market needs motivation to buy STS
Redacted
- Jingle revival event, contest, casting call; make it more relevant to new market
- Promote at teen events, sporting events
- Decrease sample size so that they can still use it but not have a short term supply; need to get the consumer to go buy more after trying
 - Salt and pepper packets
 - Ketchup packet sized
- Different shape: try unique powder cylinder (differentiate from P/L)
- Lots of Sport potential:
 - Promos on shoes or athletic gear
 - Sporting event sampling (exit/entrance samples)
 - Channel breaker display
 - Buy celebrity sponsorship
 - ESPN radio
 - Talk to Jack Weekly for sport connections
- Target brides; under stress so they need powder
 - Ads in bride magazines
- Link with a manicure/pedicure chain, beauty product
 - If it will become a beauty product, what is the message?
- Sampling at retailers like BJ's, Costco, Sam's
- Education to younger consumers is important

- Times Square Billboard
- Play jingle in subway stations, hire people to look like street performers singing about Shower
- Arena signage
- Talk radio personality endorsements (like Gold Bond)
 - Can go for sports casters or even weather forecast
 - "Weather forecast brought to you by SHOWER to SHOWER®"
 - Set it up to do the weather on hot, humid days
- Weather Channel, either on line or on TV
- Other publicity styles: Vitamin water and the NY post
- Regis and Kelly samples (always under hot lights)
- Ellen DeGeneres Show – product placement/integration
 - Really "big finish" – tie-in
 - She might need it after her dancing segment
 - Help re-write the jingle
- Oxygen TV sampling, sponsorship
- Reality TV – product placement?
 - Survivor
 - Queer Eye
 - The Amazing Race
- Figure out best radio spot timing: morning or night reminders?
- "Flip book" advertising next to train lines
- Stress platform: how to keep cool under pressure
 - Promos with political campaigns
 - Tiger Woods
 - Martha Stewart
- Fashion dos and don'ts, before and after shots, what Shower will do for you
- I-com database – f/u with Jean
- New potential for wipes?
- Do a deeper dive into finding out what is important to Redacted women and the younger ones in particular
- Ulta has created edible powder, sells for about \$25/bottle and actually sells out
- Involvement with military – could be big market
- Packaging - make it gender neutral
- Sampling at men's health clubs

EXHIBIT 4



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18-4RB

We love babies.

And we understand how to soothe and relieve baby soft skin. That's why JOHNSON'S® Baby Powder is designed to gently absorb excess moisture helping skin feel comfortable. Our incredibly soft, hypoallergenic, dermatologist and allergy-tested formula glides over skin to leave it feeling delicately soft and dry while providing soothing relief.



WARNING: Keep powder away from child's face to avoid inhalation, which can cause breathing problems. Avoid contact with the eyes. For external use only.



To Use:

1. Shake powder directly into your hand, away from the face, before smoothing onto the skin.



2. Close tightly after use, store in a cool, dry place.

SAFETY TIP: Keep out of reach of children.

Do not use if quality seal is broken.

Ingredients: Talc, Fragrance



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Talc Made in China

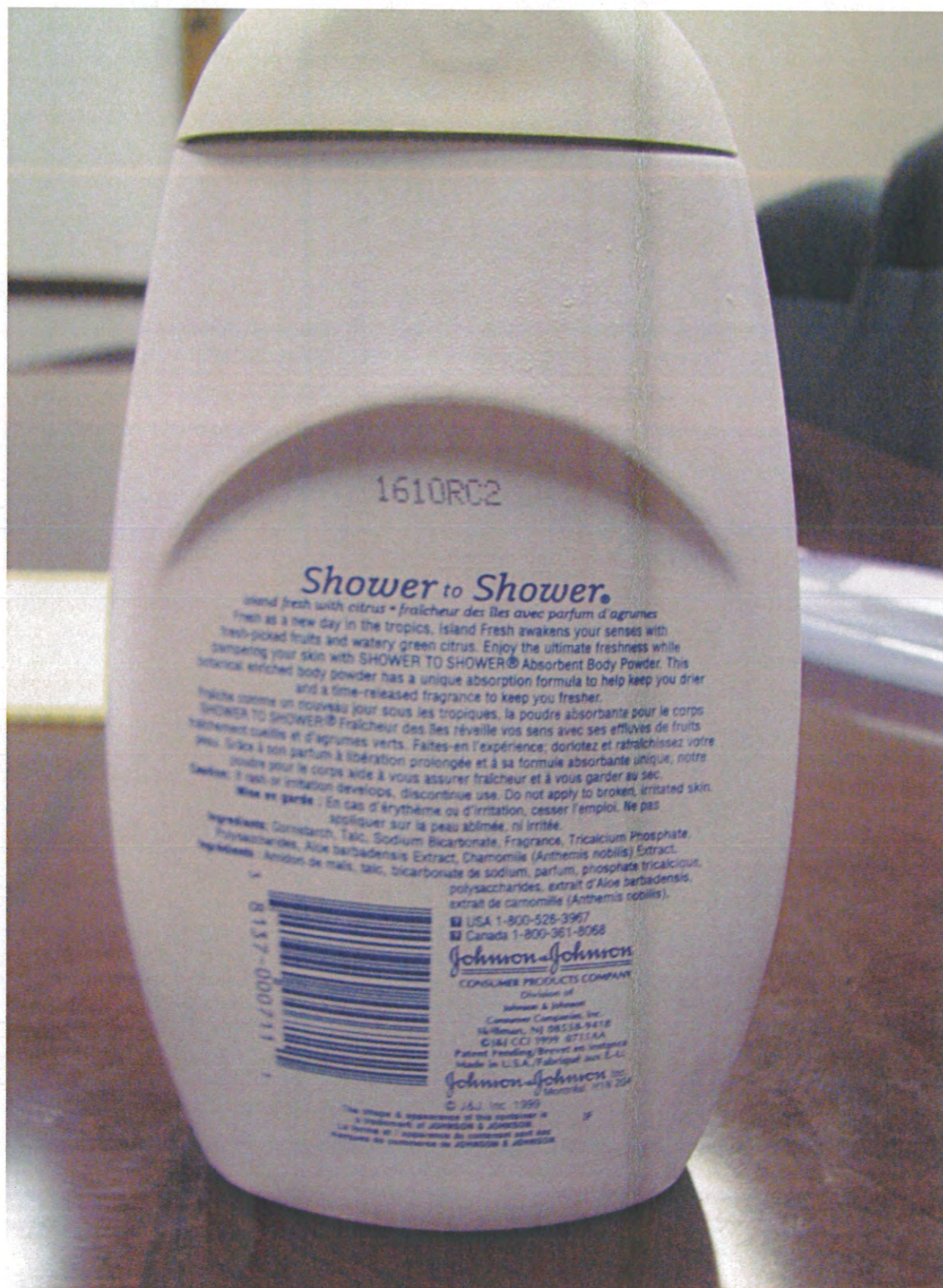
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EXHIBIT 6

*The Journal of Obstetrics and Gynaecology
of the British Commonwealth*
March 1971. Vol. 78. pp. 266-272.

TALC AND CARCINOMA OF THE OVARY AND CERVIX

BY

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Velindre Memorial Centre for Cancer Research

A. C. TURNBULL, *Professor of Obstetrics and Gynaecology*
Welsh National School of Medicine

AND

K. GRIFFITHS, *Director*
Tenovus Institute for Cancer Research, Welsh National School of Medicine, Cardiff

Summary

An extraction-replication technique was used to examine tissue from patients with ovarian and cervical tumours. In both conditions talc particles were found deeply embedded within the tumour tissue. The close association of talc to the asbestos group of minerals is of interest.

THE development in this laboratory of an extraction-replication technique (Henderson, 1969) for the study of foreign particles within tissues has allowed the *in situ* identification of crocidolite asbestos within the tissue of various mesotheliomas (Henderson *et al.*, 1969) removed from patients who had been concerned with the manipulation of asbestos in industry. This technique has now been applied to the study of tissue from ovarian and cervical carcinoma.

MATERIALS AND METHODS

Tissue

The tissue studied was obtained from patients with cancer of either the ovary or the cervix, and was first prepared as paraffin sections for normal routine histological examination but was unstained. Sections were then stained for histological assessment in the usual manner, and adjacent unstained tissue prepared for electron microscopy.

Replication Technique

The extraction-replication procedure has been described (Henderson, 1969). Sections of tissue were immersed in xylene and in ethanol, and the dehydrated tissue was then embedded by

impregnating the section on to the surface of a thin sheet of acetone-softened cellulose acetate, mounted on a glass slide, and left to harden. On removing the slide, the embedded tissue was left in the cellulose acetate. The tissue was then outlined with thin strips of Scotch tape to form a shallow well, and a 10 per cent (v/v) polyvinyl alcohol (PVA) solution applied. When the PVA had hardened it was stripped from the section providing a replica of the tissue surface. Foreign particles associated with the tissue are often removed with the PVA during this stripping process.

A complete sequential examination through the embedded tissue is possible by taking successive strippings. These surface replicas were then preshadowed with platinum, a carbon film deposited for strength, and the PVA removed by floating the replica in a hot water bath. Replicas were mounted on electron microscope grids for examination, using the AEI-6B microscope.

RESULTS

No asbestos particles were found in any of the tissue studied. Particles of talc were identified in approximately 75 per cent (10 of 13) of the

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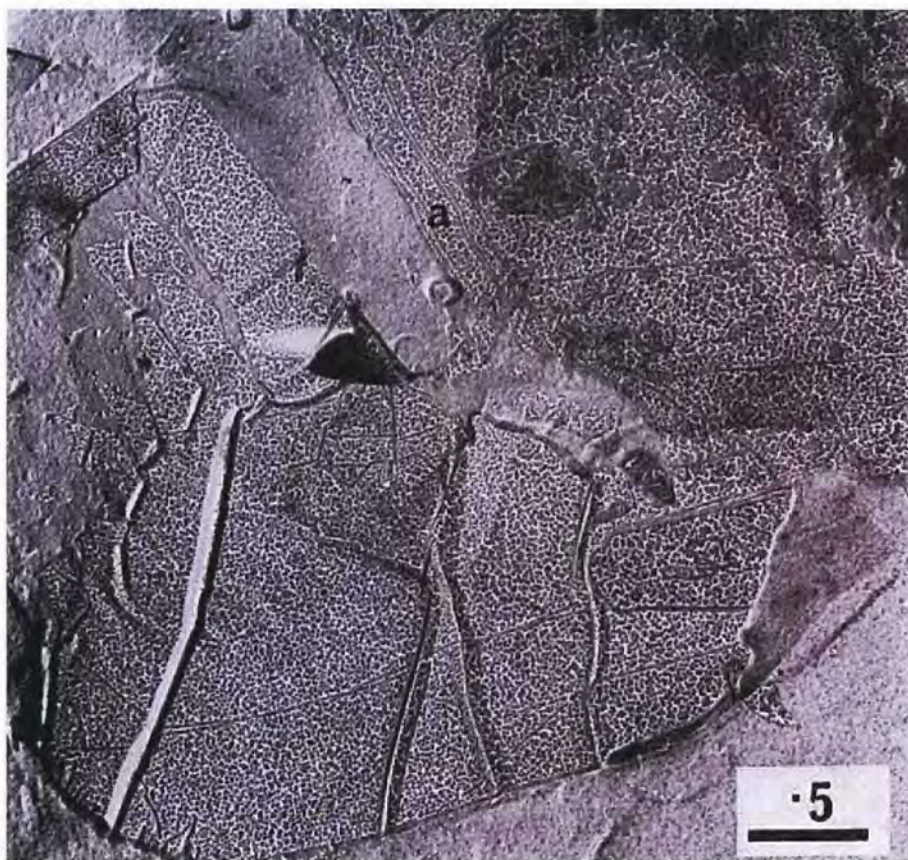


FIG. 1
Typical decoration pattern on a particle of natural talc. Numerous crystal lattice planes are shown (a). ($\times 30\,000$.)
Scale refers to $1.0\,\mu$.

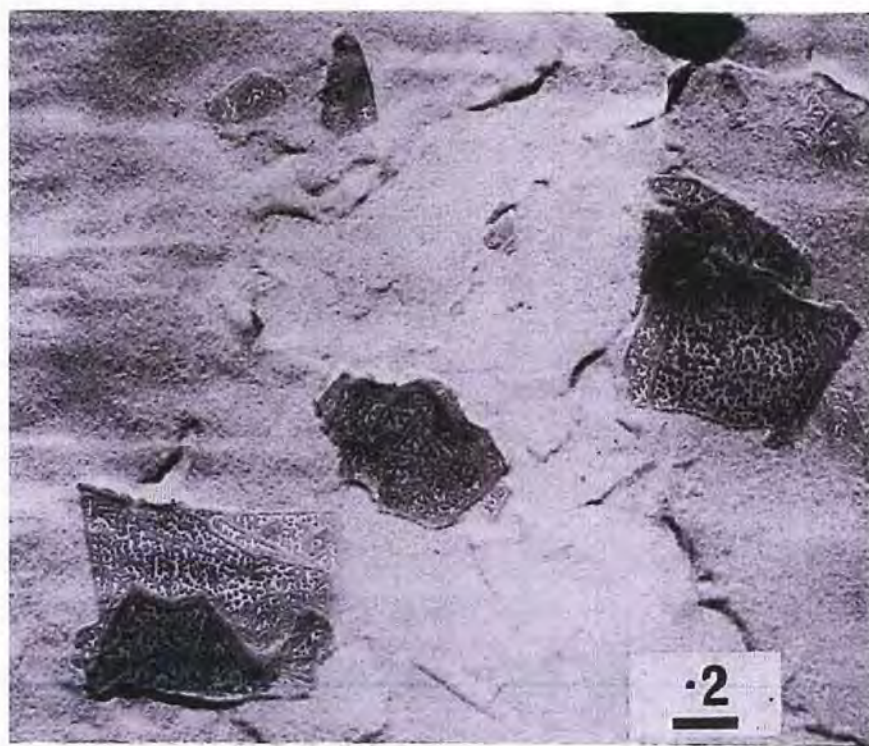


FIG. 2
Commercial talc preparations illustrating the decoration pattern. ($\times 40\,000$.)



FIG. 3

Micrograph of tissue from a serous papillary cystadenocarcinoma of the ovary removed from a 27-year-old female. No previous abdominal operations had been carried out. The decoration pattern and lattice planes are shown. ($\times 30\,000$.)

ovarian tumours. Using the replication technique identification of talc is possible because of the characteristic "decoration pattern" induced by the evaporation of platinum *in vacuo* on the crystal surface. Figure 1 shows this pattern on a particle of *natural* talc and the distinctive lattice planes of the crystals. Anthophyllite asbestos, which is known to be converted naturally to talc, is the only crystalline material which is at present indistinguishable from talc by using the replication technique. The decoration pattern on material from a commercial talc preparation is also demonstrated in Figure 2.

Material found within the ovarian tumours

and identified as talc is illustrated in Figure 3. The talc particles were found deep within the tumour tissue. Some were as small as 1000\AA in size but they were generally within a range from 1000\AA to $2\text{ }\mu$.

Talc particles were also found embedded within tumours of the cervix. Figure 4 shows one such particle embedded in a capillary wall within the tumour, and Figure 5 illustrates the decoration pattern of the particle at a higher magnification. Crystals as large as $5\text{ }\mu$ were found in tissue from the cervical tumours and were generally larger than those seen in the ovarian tumours. Talc crystals were found in

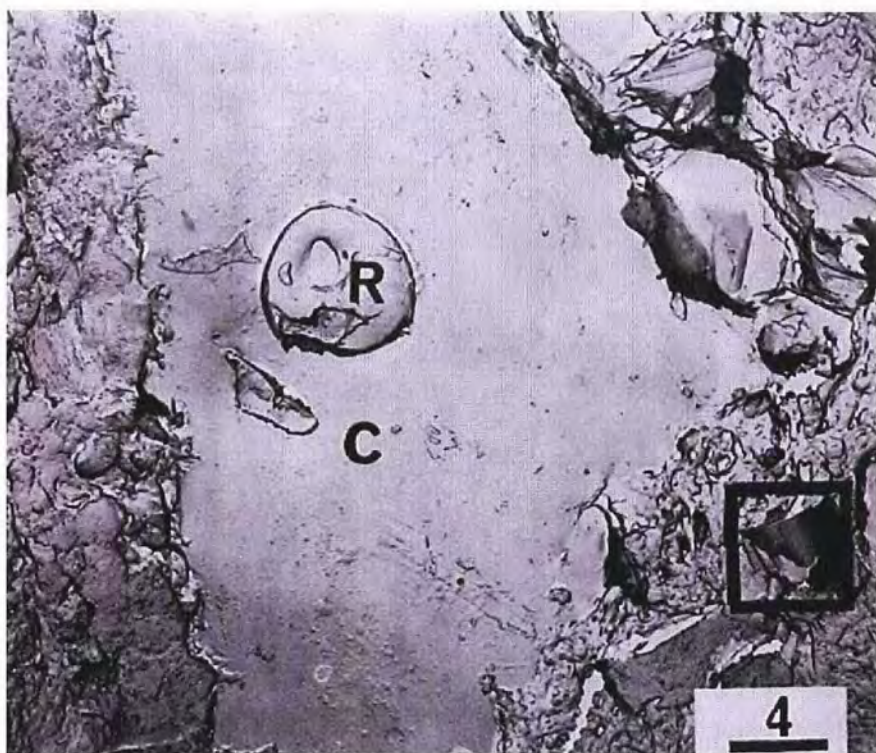


FIG. 4
Micrograph of tissue from a squamous-cell carcinoma of the cervix from a 62-year-old female. C—capillary, R—red cell. The particle of talc can be seen in the wall of the capillary. ($\times 3500$.)



FIG. 5
A higher magnification of the talc particles outlined in Fig. 4. The typical decoration pattern is shown. ($\times 40\,000$.)



FIG. 6
Talc particles found in
tissue from a pneumo-
coniotic lung. ($\times 30\,000$.)

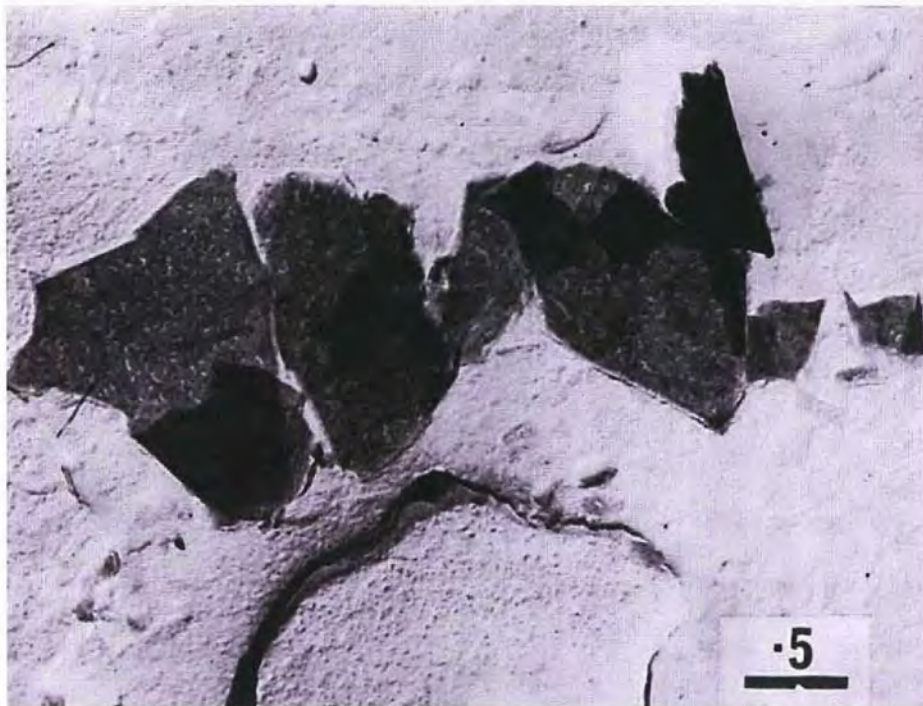


FIG. 7

Micrograph from the deepest part of an extensive papillary adenocarcinoma entirely replacing the endometrium in a 58-year-old woman, 8 years postmenopausal. Both ovaries were enlarged by hilar metastases, showing histological features similar to the primary endometrial lesion. Numerous talc particles were found in the primary endometrial carcinoma, but none in the metastatic ovarian tumours. ($\times 26\,000$.)

approximately 50 per cent of the cervical tumours examined (12 of 21) but it must be realized that these particles are extremely minute, often with the dimensions of viruses, and only small regions of the tumour tissue could be studied. Approximately ten replication "stripings" for electron-microscope examination are usually taken from each thin section of the tissue. Figure 6 illustrates the use of the technique in the examination of pneumoconiotic lung tissue from a patient whose industrial history indicated long exposure to Norwegian talc.

Many particles of talc were found concentrated in the deeper layers of a primary carcinoma of the endometrium (Fig. 7) whereas extensive studies of a secondary tumour in the ovary in the same patient did not show the presence of talc. Application of the technique to "normal" ovarian tissue removed from patients with breast cancer has also shown talc particles in 5 of 12 such tissues studied. Extensive study at high magnification with the electron microscope is, however, required for evaluation of a replica and particles could easily be missed.

The application of electron-microscope microanalysis (EMMA-AEI, Harlow, England) to the particles extracted by the replication technique has provided preliminary evidence that the crystals contain magnesium and silicon, talc being a magnesium silicate.

DISCUSSION

The possibility that the increasing incidence of carcinoma in western society may be related to a corresponding increase in the use of asbestos (Graham and Graham, 1967) is of interest, especially with regard to pleural and peritoneal mesotheliomas in workers exposed to crocidolite asbestos in industry (Wagner *et al.*, 1960; Elwood and Cochrane, 1964). There have been a number of reports about the relationship between asbestos and carcinogenesis (Smith *et al.*, 1965; Jacob and Anspach, 1965). However, the identification of asbestos fibres within tissue is extremely difficult. Fine particles embedded within tumour tissue are usually beyond the limits of resolution of the optical microscope, and tissue incineration, followed by electron microscopy of the isolated particles, may be unreliable if chemical changes are

induced by the procedure. Using normal light microscopy, identification of asbestos particles is based on the presence of characteristic ferritin bodies on some of the fibres, although these cannot easily be distinguished from similar bodies around elastin fibres (Henderson *et al.*, 1970). This procedure may not, however, be as unreliable as the use of polarized light for the demonstration of brightly illuminated "birefringent crystals of asbestos".

The replication technique (Henderson, 1969) failed to show asbestos fibres in the ovarian neoplasms studied. On the other hand, there was good evidence for the presence of talc, often indistinguishable from anthophyllite asbestos, within the ovarian tissue. (Anthophyllite is converted naturally to talc.) The talc particles were found localized deep within tumour tissues, and not universally dispersed throughout the tumour. The talc particles in the ovary were generally much smaller than those found in the tissue from the tumours of the cervix.

The relationship between asbestos and mesotheliomas appears well established, and the replication technique has provided unequivocal evidence for the presence of fibres within such tumours. This technique has also produced evidence for the presence of talc in tissue from pneumoconiotic lungs of a patient with an industrial history of exposure to Norwegian talc (Henderson *et al.*, 1970). The presence of mica, kaolin and asbestos fibres were also identified in tissue from these pneumoconiotic lung tissue.

Although it is impossible to incriminate talc as a primary cause of carcinomatous changes within either the cervix or the ovary on the preliminary observations described here, the possibility that talc may be related to other predisposing factors should not be disregarded and further investigations are obviously required.

ACKNOWLEDGEMENTS

The authors gratefully acknowledge the generous financial support of the Tenovus Organization. They also thank Dr. J. W. Dobbie, Department of Pathology, Royal Infirmary, Glasgow, for supplying a number of tissue sections, and also Mr. D. E. Evans, Department of Geology, National Museum of Wales, for the natural minerals required for reference purposes.

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EXHIBIT 7

~~RES~~
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Johnson & Johnson

JAN 25 REC'D

FEB 14 REC'D

New Brunswick, N.J.

January 18, 1974

Subject: Talc/Asbestos

Meeting with Commissioner Schmidt, FDA
January 16, 1974

Memo to File

Attendees:

for FDA: Dr. V. Wodicka, Director, Bureau of Foods
Dr. H. Eiermann*, Director, Division of Cosmetics
Technology.
Mr. J. Wenninger, Deputy Director, Division of
Cosmetics Technology.

Later: Commissioner Schmidt and the above.

for J&J: Dr. R. Fuller, Dr. G. Hildick-Smith, Dr. W. Nashed

A preliminary meeting with Dr. Wodicka and his staff was held. We traced the history of the talc/asbestos problem: Kretchmer letter; FDA Symposium, August, 1971, where Mt. Sinai people admitted that their analysis based on optical microscopy of our product was wrong and that Johnson & Johnson Baby Powder was the best talc available; and we mentioned the voluminous data which we had shared with the FDA. Dr. Eiermann and Mr. Wenninger corroborated our presentations to Dr. Wodicka.

Hummer
Dr. Eiermann then said that he has reviewed the CTFA Round-Robin test results with his microscopist, Mr. Schulze, and said that Mr. Schulze still thinks the method is valid. We pointed out that we believe that the method has some basic flaws as outlined in the CTFA comment; however, we believe that a cooperative program between FDA and industry should result in a practical solution to the problem.

* Former J&J employee in Brazil.

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Memo to File

- 2 -

January 18, 1974

We pointed out that we had developed a DTA method capable of measuring 1% chrysotile and we also believe that a step scan x-ray method can be used to detect 0.2% tremolite.

Dr. Eiermann said that they have obtained DTA equipment and x-ray equipment and that he has some reservation about allowing 1% chrysotile.

We volunteered to cooperate with his scientists in the development of the method for DTA and promised to provide a copy of a proposed publication regarding this method.

Dr. Eiermann said that his main interest at this time is to find what level of dust exposure occurs in the process of dusting a baby and that they would like to use the data to calculate allowable asbestos using 5 fibers per ml (OSHA limit) for safe exposure in the mines. We promised to provide a report on the talc dust exposure of babies. We pointed out that the data we have is based on exaggerated dusting of a whole can of baby powder and that the amount generated, namely 345 mg/ m³ may be excessive. We said that we are currently attempting to make the same calculation he proposed to the data. Our very preliminary calculation indicates that substantial asbestos can be allowed safely in a baby powder.

Dr. Wodicka appeared skeptical of Dr. Eiermann's approach to the problem. He implied that what is safe for a miner may not be safe for a baby.

Dr. Eiermann also mentioned that they were carrying out some studies in-house using an air sampler to assess the dust exposure and were having some difficulties in determining it.

Dr. Hildick-Smith reviewed the current knowledge on the biology of talc and indicated that talc had a low order of toxicity when evaluated in cell culture systems, that animal studies had been conducted which confirmed the cell culture studies, and that long-range inhalation studies in rats by MRC and in hamsters by J&J were being conducted in England and in the U.S.A. and that the results will be available in 1975. It was pointed out that two separate epidemiological studies had been conducted on talc miners, one by Dr. Kleinfeld and the other by Dr. Green at the University of Vermont School of Medicine in Burlington. The data obtained from both studies indicated that, where miners in the Kleinfeld study had been exposed to talc dust for an average of about 17 years and in the Green study for about 7 years, there appeared to be no significant impairment of the miners' health. Utilizing these data, the known information

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January 18, 1974

concerning the amount of talc to which infants were exposed and their respiratory capacity, miners were exposed for a period of approximately 1,000 times that of an infant. The dose respired by the miner is approximately 11,000 times that respired by the infant. It was brought out that critical review of all the world literature failed to show any evidence of adverse health effects following the normal use of cosmetic talcs.

Dr. Hildick-Smith indicated that he was writing a review article on talc and that a copy of the manuscript would be sent to the FDA for their files.

Dr. Fuller stressed Johnson & Johnson's policy of full cooperation with FDA and that if the results of any scientific studies show any question of safety of talc, Johnson & Johnson will not hesitate to take it off the market.

A meeting was then held in Dr. Schmidt's office. The proceedings were similar to that which took place in Dr. Wodicka's office.

Dr. Schmidt asked for information on our Vermont mine: location (Windsor, Vt.), kind of talc (platey talc), processing (froth flotation to maximize platey talc). He wanted to know whether we sell our talc to other companies (cosmetic beneficiated grade is not sold to other companies; other locations in the Windsor mine are used to supply industrial grade talc).

Dr. Fuller pointed out that our meeting is not a "crisis" meeting. The Commissioner appeared to appreciate that. Dr. Fuller again stressed Johnson & Johnson's policy of full cooperation with the FDA which preceded the Kretchmer incident, namely, the Tenovus report where Dr. Hildick-Smith had called Dr. Simmons at the time we first heard of it. We reviewed briefly the Tenovus data (unreliable talc particle identification technique, presence of mineral particles in the tissue-fixing baths, lack of formal education of the principal investigator).

Dr. Hildick-Smith also commented briefly on the article relating stomach cancer in the Japanese and pointed out that this was generally discredited by scientists and that there was no information in the world literature or in animal studies completed to indicate talc produced cancer.

✓ Dr. Schmidt said that the FDA could come under pressure from consumer or other groups and that they were particularly vulnerable when there were minimal, inadequate or no scientific data in a specific area. He had, however, developed a tactic by which he publishes in the Federal Register any scientific attack on the FDA in the hope that members of the scientific community could provide data to assist the FDA.

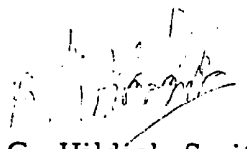
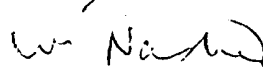
Memo to File

- 4 -

January 18, 1974

He appreciated the Johnson & Johnson visit and our expression of interest to assist the FDA where possible. He welcomed the opportunity of having a source of scientific information on which he could rely if the occasion arose. He indicated the immediate interest of the FDA in developing a method for assessing asbestos in talc. He pointed out that additional information being developed by Johnson & Johnson and others would meet the possible future need if talc per se is attacked. As there were some scientific data and good scientific studies in hand, the scientific community would be well prepared to withstand any onslaught concerning talc.

The meeting ended on a very cordial note and appreciation by the FDA officials of Johnson & Johnson's visit and willingness to cooperate with the agency in developing methods and providing information concerning talc technology.


G. Hildick-Smith
W. Nashed

cw


cc: Dr. R. A. Fuller
Dr. A. Goudie
Dr. G. Hildick-Smith
Mr. D. D. Johnston 
Mr. G. Lee
Dr. D. Petterson
Mr. S. Smoyer
Dr. T. Shelley
Mr. H. Stolzer

EXHIBIT 8

Johnson & Johnson

return to
New Brunswick, N.J.
December 3, 1975

Subject: Talc in the Ovaries

Dr. D. R. Petterson

Attached is a letter received from Dr. Keith Griffiths, who is Director of the Tenovus Institute for Cancer Research in Cardiff. The letter arrived in response to a small donation I had sent the Cardiff Scientific Society with the main objective of trying to determine what research is in actual fact being conducted at the Tenovus Institute.

It might be of value to identify the precise scientific data available to Tenovus concerning talc and ovarian cells. We are not budgeted to support the research outlined and shall so inform Griffith if this meets with your approval.

Gavin Hildick-Smith

GHS/cd
Att.

cc:
Mr. G. Lee
Dr. F. R. Rolle
Dr. B. Sample

→ G. Lee,

It would be wise

to know ahead of time, just what Gavin intends doing. Did you know he was planning to donate to the C.S.S.? It has certainly given J&J the opening to put us on notice re the talc /ovary problem.

*No - we were not asked
We were asking this at the J&J advisory group meeting*

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EXHIBIT 9

Talc and Ovarian Cancer

Supplementary questions and answers
Prepared 20.10.97

Background

On 22nd October 1997, Face Value will air a programme, which will discuss a potential link between talc and ovarian cancer. This issue has been around for many years and there has been a full FDA review of all of the research available. This review has concluded that there is absolutely no causal link between talc and ovarian cancer. This is an industry matter and is not specific to Johnson's Baby powder. The CPTA has issued a full statement on the matter and Johnson & Johnson supports this statement.

The purpose of this document is to supplement the question and answer sheet already issued by J&J corporate. It covers issues specific to what may be aired during the Face Value programme. Any questions on the link to ovarian cancer or the similarities to asbestos are contained within the corporate Q&A also attached.

Above all, the company is absolutely sure that Johnson's Baby Powder is perfectly safe for use on any part of the body, in line with the directions on the pack. There is no link to ovarian cancer either implied or actual and this is the conclusion of the independent review carried out by the FDA. Trust and safety is the basis of our company reputation and if we believed there was even the slightest risk associated with the normal use of Johnson's Baby Powder, we would not hesitate to take the necessary action.

Questions and answers in response to recent publicity. (numbered from Q.38 onwards which follows the corporate Q&A sheet)

Q.38: If you are saying that there is no link to ovarian cancer then why did the programme suggest that there is - they wouldn't just make it up would they?

A.38: That is a good question and we have challenged ourselves on the same issue. We are entirely confident of the safety of our product and all we can do to reassure you is tell you the facts: and that is that there is absolutely no link between talc and ovarian cancer. This is the view expressed by the independent FDA working party who have reviewed all of the research and is supported by the CPTA.

Q.39: Are you saying that the research is not valid in its conclusions?

A.39: What is most important here is what the independent working party who have reviewed this research have concluded. They have concluded that there is no link to ovarian cancer either implied or actual. We have also carried out our own review of the data and we support the conclusions drawn by the FDA.

Q.40: Why did Johnson & Johnson decline to be interviewed by Face Value?

A.40: The talc issue is a general industry issue and is not specific to Johnson's Baby Powder. The CPTA issued an industry response to Face Value, which we support. We are more than happy to talk to our consumers directly (as

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I am doing with you now) but it is not our corporate policy to talk to our consumers through the medium of television programmes like Face Value.

Q.41: Why did the CPTA statement which J&J supports make no reference to the fact that the FDA went on to conclude that people should "err on the side of caution"?

A.41. The written FDA statements, which the CPTA have relied on to draw their conclusions, do not contain any such reference. If this is a personal or subsequent view verbalised by any member of the FDA then they are entitled to express that view. Ultimately we all have to take whatever action is right for ourselves. What I can assure you of however, is that Johnson's Baby Powder is perfectly safe for normal use and that the FDA formal conclusions were that there is absolutely no link either implied or actual to ovarian cancer.

Q.42: If you have known about this research since 1994 or before, why didn't you tell consumers before now or were you just worried about your sales?

A.42: We believe that our first responsibility is always to our consumers. This research has always been in the public domain and we have made no attempt to hide it. We have made every attempt to understand its implications for our consumers and can assure you that independent reviews of the research carried out by the FDA have concluded that there is no link to ovarian cancer. Trust is the basis of our company reputation and I can assure you that if there was the slightest risk to our consumers we would be the first to withdraw the product. We have done this before with Tylenol in the US.

Q.43: If there is even the slightest risk of a link to ovarian cancer why do you say that the product is safe to use on babies, particularly on babies' bottoms?

A.43: We can assure you that there is not even the slightest risk of a link to ovarian cancer. Independent studies have proven that talc cannot migrate from any area of the body to the ovaries. Johnson's Baby Powder is perfectly safe to use on your baby, in line with the normal directions on the pack.

Q.44: Why would Face Value make a programme on this subject if there is nothing to it - surely I should believe them more than I should believe you because they have the consumers' interests at heart?

A.44: That is a great question and I cannot answer it for you. Our opinion is that it is the independent conclusions of the FDA working party that are the most reliable source of the truth in this matter. This working party concluded that there was absolutely no link between the use of talc and ovarian cancer. Ultimately you have to judge the accuracy of the information you have received from the media and from us. However, I can assure you that we always have our consumers' interests at heart and that if there was even the slightest risk we would act accordingly.

Q.45: I don't care if you think that there is absolutely no risk. You should have made consumers aware of the issue - there should be directions on the pack to indicate that it is not suitable for use on certain parts of the body. Are you going to do this in the future?

A.45: Ultimately, it is not what we think that matters, but what independent sources such as the FDA think. We are extremely confident in the FDA working party conclusion that there is absolutely no risk of ovarian cancer. Johnson's Baby Powder is safe for use, in line with the normal directions on pack, on any

part of the body. Research has proven that talc cannot migrate from any part of the body to the ovaries. We are extremely confident in the safety of our product and see no need to make any changes to the current packaging.

Q.46: I have just been diagnosed with ovarian cancer and I have been using Johnson's Baby Powder for years. I am extremely angry that you knew about this years ago and that you did not inform the public. I want to know how you are going to compensate me.

A.46: I am extremely sorry to hear about your recent diagnosis. However I can assure you that there is absolutely no link between Johnson's Baby powder and ovarian cancer. This is not just our view but is supported by an independent review of all of the research available conducted by the FDA.

If the consumer is still unhappy with this response and insistent upon what we are going to do to compensate her then the appropriate response is...

Once again, I am very sorry to hear that you are suffering from ovarian cancer, however I can assure you that our product is not at fault. If you wish to take this further then that course of action is up to you and we will respond accordingly.

Q.47: How can you be totally sure that talc does not cause ovarian cancer?

A.47: We are absolutely sure for a number of reasons: firstly, an independent review of all the research available, conducted by the FDA has concluded that there is no link between talc and ovarian cancer. Secondly, in the UK and the U.S where talc is commonly used, the incidence of ovarian cancer is 15 / 100,000 women whereas in Scandanavia where talc is not used by women the incidence of ovarian cancer is higher at 21 / 100,000 women. The higher incidence of ovarian cancer in Scandanavia is linked to diet and has no connection to the use of talc.. We can absolutely assure you that there is no known or implied link between talc and ovarian cancer. If there was we would be the first to take appropriate action for the safety of our consumers.

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EXHIBIT 10

Ovarian Cancer and Talc

A Case-Control Study

DANIEL W. CRAMER, MD,*†‡ WILLIAM R. WELCH, MD,§ ROBERT E. SCULLY, MD,||
AND CAROL A. WOJCIECHOWSKI, RN‡

Opportunities for genital exposure to talc were assessed in 215 white females with epithelial ovarian cancers and in 215 control women from the general population matched by age, race, and residence. Ninety-two (42.8%) cases regularly used talc either as a dusting powder on the perineum or on sanitary napkins compared with 61 (28.4%) controls. Adjusted for parity and menopausal status, this difference yielded a relative risk of 1.92 ($P < 0.003$) for ovarian cancer associated with these practices. Women who had regularly engaged in both practices had an adjusted relative risk of 3.28 ($P < 0.001$) compared to women with neither exposure. This provides some support for an association between talc and ovarian cancer hypothesized because of the similarity of ovarian cancer to mesotheliomas and the chemical relation of talc to asbestos, a known cause of mesotheliomas. The authors also investigated opportunities for potential talc exposure from rubber products such as condoms or diaphragms or from pelvic surgery. No significant differences were noted between cases and controls in these exposures, although the intensity of talc exposure from these sources was likely affected by variables not assessed in this study.

Cancer 50:372-376, 1982.

THE POSSIBILITY that ovarian cancer may be caused by exposure to certain hydrous magnesium silicates such as talc and asbestos has been raised by several researchers.¹⁻³ The lack of epidemiologic studies regarding this hypothesis prompted us to investigate talc exposure in a case-control study of ovarian cancer.

Methods

The cases studied were women with ovarian cancer, diagnosed between November 1978 and September 1981 and identified through the pathology logs or tumor boards of twelve participating hospitals in the Greater Boston area. The study was restricted to English-speaking residents of Massachusetts ranging in age from 18 to 80 years. During the study period, 297 eligible cases were identified. Physicians denied permission to contact their patients in 13 instances. Fourteen patients declined to participate, and 14 other patients had died or moved before they could be contacted.

For each of the 256 interviewed cases, slides of the surgical specimens were reviewed by two authors (W.R.W. or R.E.S.). Eighteen cases were excluded as nonovarian primaries. Each ovarian tumor was classified according to the Histological Classification of Ovarian Tumors of the World Health Organization.⁴ The present analysis was restricted to 215 white women with epithelial cancers, including 39 with tumors of borderline malignancy and their matched controls.

Control cases were identified through the Massachusetts Town Books, annual publications that list residents by name, age, and address. Controls were selected randomly from those women who matched cases by precinct of residence, race, and age within two years. Additionally, it was required that a subject be excluded

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as a control if she had had a bilateral salpingo-oophorectomy, but subjects were not excluded because of prior hysterectomy or other types of pelvic operations. Women who had had pelvic operations were generally confident in their knowledge of whether their ovaries had been removed, but the nature of the operations could not be verified by hospital records in each instance. Women whose statements could not be verified were included or excluded on the basis of their recollection of the surgery. The 215 controls in this study were eventually obtained from a total of 475 potential controls identified through the Town Books. Fifty-six (12%) of the total could not be reached because they had moved, died, or had disconnected or unlisted phones. Twenty-nine (6%) of the total were ineligible because of a history of bilateral salpingo-oophorectomy, while 20 (4%) were of the wrong age or race or did not speak English. Of the total potential controls, 155 (33%) refused to participate. If the 215 cases are characterized as to ease of matching, 121 (56%) cases were matched with no refusals, 58 (27%) were matched after one refusal, and 36 (17%) were matched only after two or more refusals.

Interviews were conducted personally to assess a number of factors from the menstrual and reproductive history, medical and family history, and environmental exposures. This report will deal only with the results of several questions related to potential or definite talc exposure by way of contraceptive practices, operations, or perineal hygiene. Subjects were stratified by potential confounders described below, and adjusted relative risks associated with these exposures were calculated by the Mantel-Haenszel procedure as adapted by Rothman and Boice.⁵ To accommodate other confounders as well as the matched design in the data collection, logistic analysis for matched data as described by Breslow *et al.*⁶ was also employed.

Results

The average age (and standard error of the mean, SEM) for cases was 53.2 (1.0) years and for controls,

TABLE 1. Characteristics of Cases and Controls

Characteristic	Cases (Total = 215)		Controls (Total = 215)	
	No.	%	No.	%
Educational level (completed college)	48	22.3	49	22.8
Religion (Roman Catholic)	126	58.6	128	59.5
Marital status (never married)	46	21.4	24	11.2
Nulliparous	78	36.3	39	18.1
Menopausal status (postmenopausal*)	137	63.7	129	60.0

* Postmenopausal at time of diagnosis for cases or for interview for controls.

53.5 (1.0) years. Table 1 shows other characteristics of subjects. Controls were comparable to cases in educational level and religion. Cases and controls differed significantly in marital status and parity with parity being the more important discriminator between them. Sixty-four percent of the cases were postmenopausal at the time of diagnosis, whereas 60% of controls were postmenopausal. Of these, 15 cases and 20 controls had had an artificial menopause. Parity and menopausal status were considered important potential confounders in this analysis and were adjusted for as described above.

Relative risks associated with potential talc exposure from contamination on rubber products are explored in Table 2. Although surgical gloves of recent vintage are dusted with starch, talc contamination may still be found.⁷ Thus, a history of pelvic operations (appendectomy, cesarean section, hysterectomy, and other operations on internal genital organs other than bilateral salpingo-oophorectomy) was determined in cases and controls. Excluding operations associated with the diagnosis or treatment of the ovarian cancer among the cases, no excess in the occurrence of pelvic operations was noted. The greatest opportunity for talc exposure from surgery occurred before 1950, when talc was the

TABLE 2. Relative Risks (RR) for Common Epithelial Ovarian Cancers Associated with Potential Talc Exposure from Contamination on Rubber Products

Exposure	Cases		Controls		Crude RR	Adjusted RR*	95% Confidence limits
	Total	No. (%) with exposure	Total	No. (%) with exposure			
Pelvic surgery	215	78 (36.3)	215	75 (34.9)	1.06	1.17	(0.76-1.79)
Pelvic surgery (prior to 1950)	215	51 (23.7)	215	48 (22.3)	1.08	1.12	(0.69-1.82)
Use of condom†	169	19 (11.2)	191	30 (15.7)	0.68	0.77	(0.41-1.44)
Use of diaphragm†	169	37 (21.9)	191	35 (18.3)	1.24	1.19	(0.69-2.05)

* Adjusted for parity (nulliparous, parous) and menopausal status (pre- and postmenopausal).

† Restricted to subjects who had ever been married.

TABLE 3. Relative Risks (RR) Associated with Using Talc for Storage Among Diaphragm Users* by Duration of Use of Diaphragm

Duration of diaphragm use	Cases		Controls		Crude RR	Adjusted RR†	95% Confidence limits
	Total	No. (%) who used talc on diaphragm	Total	No. (%) who used talc on diaphragm			
Total diaphragm use less than five years	13	6 (46.2)	21	8 (38.1)	1.39	1.82	(0.42-8.00)
Total diaphragm use five or more years	27	16 (59.3)	19	11 (57.9)	1.06	1.23	(0.36-4.17)
All users	40	22 (55.0)	40	19 (47.5)	1.35	1.56	(0.62-3.88)

* Includes all women who used diaphragm regardless of marital status.

† Adjusted for parity and menopausal status.

predominantly used dusting powder for surgical gloves. However, no significant excess of pelvic operations prior to 1950 was observed for cases.

The patients (cases) who, at sometime, had been married, chose condoms less frequently and diaphragms more frequently for contraception than the control group, but neither difference was statistically significant. Condom use is not necessarily associated with talc exposure. Not all brands of condoms are dusted with talc, and lubricants could affect the shedding of talc from the condom. Unfortunately, details on specific brands of condoms were not obtained. Similarly, talc exposure is not a necessary consequence of diaphragm use. We inquired specifically about the practice of dusting the diaphragm with talc for storage after use (Table 3). Among all subjects who had used a diaphragm, there was no significant excess of cases who regularly stored their diaphragm using talc, nor was any greater risk associated with this practice observed among women who had used the diaphragm for longer durations. Before the risk from this exposure can be adequately assessed, greater detail is needed including frequency of use and whether the powder was washed off prior to use. Furthermore, contraceptive jellies used with the diaphragm could affect the transport of talc in the genital tract.

Hygienic practices involving talc were also studied. Specifically, we inquired whether women had regularly used talc as a dusting powder on the perineum or regularly dusted sanitary napkins with talc (Table 4). Ninety-two (42.8%) of the cases had talc exposure by either or both of these routes compared with 61 (28.4%) of the controls. The adjusted relative risk was 1.92 ($P < 0.003$) with 95% confidence limits of 1.27-2.89 compared to subjects who had neither exposure. Sixty (27.9%) cases and 48 (22.3%) controls had either used talc for dusting or on napkins but not both. This difference yielded an adjusted relative risk of 1.55, which was of borderline significance ($P = 0.06$). The greatest risk occurred in women who had both exposures (use on the perineum and on napkins) compared to women who had neither exposure. Thirty-two (14.9%) of cases were in this category compared with 13 (6.0%) controls, for an adjusted relative risk of 3.28 ($P < .001$) and 95% confidence limits of 1.68-6.42. The histologic characteristics of tumors developing in women with perineal exposure to talc did not differ significantly from those in women without perineal exposure to talc (Table 5). In addition, the proportion of cases with tumors of borderline malignancy was identical among those with and without perineal exposure to talc. Twenty-two (18%) of 123 cases without the exposure had tumors of bor-

TABLE 4. Relative Risks (RR) for Common Epithelial Ovarian Cancers Associated with Talc Exposure in Perineal Hygiene

	Types of perineal exposure				
	No perineal exposure	Any perineal exposure	As dusting powder but not on napkins	On napkins but not as dusting powder	Both on napkins and as dusting powder
Cases (Total = 215)	123 (57.2%)	92 (42.8%)	43 (20.0%)	17 (7.9%)	32 (14.9%)
Controls (Total = 215)	154 (71.6%)	61 (28.4%)	34 (15.8%)	14 (6.5%)	13 (6.0%)
Crude rr	1	1.89	1.58	1.52	3.08
Adjusted RR*	—	1.92	1.55		3.28
95% confidence limits	—	(1.27-2.89)	(0.98-2.47)		(1.68-6.42)

* Adjusted for parity and menopausal status.

derline malignancy compared to 17 (18%) of 92 with the talc exposure.

Discussion

The argument linking talc and ovarian cancer includes four elements: the chemical relationship between talc and asbestos, asbestos as a cause of pleural and peritoneal mesotheliomas, the possible relation between epithelial ovarian cancers and mesotheliomas, and the ability of talc to enter the pelvic cavity. The mineral talc is a specific hydrous magnesium silicate chemically related to several asbestos group minerals and occurring in nature with them. Generic "talc" is seldom pure and may be contaminated with asbestos, particularly in powders formulated prior to 1976.^{8,9}

Epidemiologic studies have clearly linked lung cancer and pleural and peritoneal mesotheliomas with asbestos exposure.¹⁰ An excess of similar pulmonary lesions has been reported in talc workers and seems to be correlated with the amount of asbestos contamination in the talc deposits worked.¹¹ Graham and Graham¹ were able to induce ovarian neoplasms in guinea pigs with asbestos and suggested that ovarian cancer could be related to asbestos exposure, noting the similarity between mesotheliomas and ovarian cancers. Parmley and Woodruff¹² further emphasized this similarity and popularized the pelvic contamination theory, which proposed that environmental carcinogens might enter the pelvic cavity via the genital tract. Years earlier it had been observed that inert carbon particles placed in the vagina immediately prior to hysterectomy could be recovered from the fallopian tubes.¹³ Although greeted with skepticism, the finding of talc particles embedded in normal and abnormal ovaries suggests that talc is a substance that can enter the pelvic cavity via the vagina.²

Although no consensus concerning the risks of talc has emerged from letters, editorial and articles,^{3,14-16} participants in the discussion have agreed upon the need for epidemiologic studies of ovarian cancer and talc exposure. In this case-control study of ovarian cancer of the epithelial variety, we investigated several sources of potential talc exposure. Among these, the only significant finding was an association between ovarian cancer and hygienic practices involving the use of talc on the perineum. It is especially notable that women who regularly had both dusted their perineum with talc and had used it on sanitary napkins had more than a three-fold increase in risk compared to women with neither exposure. Several potential biases must be considered in interpreting this association.

The observation by Wynder *et al.*¹⁷ that menstrual characteristics may differ between women with ovarian cancer and controls might suggest that such differences may confound the association between perineal use of

TABLE 5. Characteristics of Ovarian Cancer in Women with and without Perineal Exposure to Talc

	No perineal use of talc	Any perineal use of talc
	No. (%)	No. (%)
Serous	66 (53.7)	45 (48.9)
Mucinous	16 (13.0)	14 (15.2)
Endometrioid and clear cell	32 (26.0)	24 (26.1)
Other and undifferentiated	9 (7.3)	9 (9.8)
Total	123 (100)	92 (100)

talc and ovarian cancer. We found that menstrual characteristics of cases and controls were virtually identical in this study. Fifty-three (24.7%) cases complained of moderate or severe dysmenorrhea compared to 56 (26.0%) controls. Twenty-five (11.6%) cases complained of irregular periods compared to 32 (14.9%) controls. The average numbers (and SEM) of days of flow and cycle length were, respectively, 4.9 (0.1) and 28.9 (0.3) days for cases and 4.9 (0.1) and 29.6 (0.3) days for controls.

Since entry of talc into the pelvic cavity is prevented by hysterectomy or tubal ligation, it might also be argued that the inclusion of subjects with pelvic surgery in the analysis may obviate any association between talc and ovarian cancer. It should be noted that such surgery generally occurred near the end of reproductive life for both cases and controls, probably after most significant talc exposure had already occurred. The exclusion of such subjects from the analysis did not substantially alter the observed associations. For example, the adjusted relative risk for the use of talc both on the perineum and sanitary napkins was 2.79 ($P < 0.003$) in the group without pelvic surgery compared to 3.28 observed for the entire group.

In terms of other confounders, the association persisted after adjustment for menopausal status and parity. We also applied multivariate logistic regression for paired observations.⁶ The maximum likelihood estimate of relative risk associated with any perineal use of talc was 1.61 ($P = 0.03$) with 95% confidence limits of 1.04–2.49 after simultaneous adjustment for religion, marital status, educational level, ponderal index, age at menarche, exact parity, oral contraceptive or menopausal hormone use, and smoking.

Our sample of cases represents more than 50% of ovarian cancer cases diagnosed in Boston residents in the study period. Therefore, it is difficult to conceive of a plausible bias in the selection of cases that would yield this excess use of talc. There is reason for concern that the high refusal rate among the controls may have introduced a selection bias among the controls. But,

when we restricted the analysis to the 121 cases who were matched without a control refusal, we again found a significant association between talc use and ovarian cancer. For women who had used talc both in dusting and on the perineum we found an adjusted relative risk of 2.44 ($P < 0.05$). Interviewer bias is also unlikely to explain the association. Of the 18 women who were initially interviewed as ovarian cancer cases but later excluded as having metastatic tumors to the ovary, only one (5.6%) had both perineal and napkin exposure as compared with 15% in cases and 6% in controls.

Experimental data which might bear on the carcinogenicity of talc come primarily from models using pleural implantation of various minerals in rats.¹⁸ These data suggest that carcinogenicity is dependent primarily upon the shape of the particles with long thin fibers such as those occurring in crocidolite asbestos being most carcinogenic. Talc consists primarily of plates but may contain fibers, although voluntary guidelines to limit the content of asbestiform fibers in consumer talcums were proposed by the cosmetics industry in 1976.¹⁹

If talc is involved in the etiology of ovarian cancer, it is not clear whether this derives from the asbestos content of talc or from the uniqueness of the ovary which might make it susceptible to carcinogenesis from both talc and other particulates. With ovulation entrapment of the surface epithelium of the ovary into the ovarian stroma occurs. If present, talc or other particulates might be incorporated into these inclusion cysts. Apparently implantation of foreign bodies into the lumens of epithelial lined organs provides a favorable environment for carcinogenesis.²⁰ Alternatively, talc might serve to stimulate entrapment of the surface epithelium and act in the same way that "incessant ovulation" has been proposed as an etiologic factor for ovarian cancer.²¹ Given the histologic and clinical diversity of ovarian cancer, talc exposure is unlikely to be the only cause. Undoubtedly, reproductive experiences such as pregnancies and, perhaps, oral contraceptive use play a role in its etiology.²¹⁻²³ The possibility that talc exposure interacts with these variables deserves further investigation.

It is hoped that this report will stimulate further study of talc exposure in relation to ovarian cancer. Animal studies would be helpful to determine whether and under what circumstances ovarian tumors may be induced by various talc preparations. Epidemiologic studies should focus on opportunities for excessive vaginal contamination with talc such as when it is repeatedly used in perineal dusting powders or sprays and in or on tampons, sanitary napkins, or other products intended for

intravaginal use. More precise details on the exact nature and frequency of the exposure and the amount and specific brand of powder used are essential. Opportunities for talc exposure are widespread and pervasive,²⁴ but that should not discourage epidemiologists from studying this potentially important exposure in relation to ovarian cancer.

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EXHIBIT 11

*Pass**James 1986 P. 5/9*TECHNOLOGICAL FORECAST

- POWDERS -

Powders refers to various inorganic and organic compounds that are applied to baby and adult skin, that are generally considered inert, and that provide skin benefits mainly from their physical characteristics, rather than their chemical compositions. This forecast does not cover medicated powders, where the powder is a vehicle for an active ingredient such as an anti-diaper rash agent.

A. PRODUCT BACKGROUND1. Attribute Factors

User end benefit attributes and product attributes have been defined for both baby and adult needs.

User:	Baby	—	Adult
Attribute:			

- | | | | |
|--|---|--|---|
| <u>End Benefits</u> | - <u>Dry slip</u> : softness, smoothness, lubricity | | |
| | - <u>Wet slip</u> : ability to convey the same tactile feel of softness, smoothness, slipperiness as found with powder on dry skin | | |
| | <table border="0"> <tr> <td>After bath,
during diaper
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change | After bath, shower |
| After bath,
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change | After bath, shower | | |
| | - <u>Absorbency</u> : take up water/wetness | | |
| | - <u>Adhesion</u> | | |
| | <table border="0"> <tr> <td>(Not considered
important)</td> <td>Vertical surface retention,
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after showering. |
| (Not considered
important) | Vertical surface retention,
esp. when applying
after showering. | | |
| | - <u>Reduce Friction</u> : prevent chafing & rubbing | | |
| <u>Product</u> | - <u>Flow</u> : ease of dispensing | | |
| | - <u>Spreadability</u> : ease of application to the skin | | |

Safety Factors

Safety of cosmetic powders has been a concern, especially among health professionals. They have decided that powders provide no health benefit. Therefore, the potential for harm from respirables or accidental over exposure should be avoided. Mothers are now being advised not to use baby powder, especially talc baby powders.

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There is also a growing concern/public awareness about airborne pollutants, including dust and other respirable particles. As this issue gains more attention, products (such as shaker top dispensed cosmetic powders) which potentially contribute to airborne dust could become expendable risks.

Retrospective studies have implicated talc use in the vaginal area with the incidence of ovarian cancer. While a CTFA sponsored animal study has shown that talc does not migrate, this concern does affect use of powders by adult women.

Based on the scientific evidence and the extensive experience in use, we believe that cosmetic powders are safe for use for babies and adults.

Normal use of cosmetic powders has not been related to safety concerns for humans.

The relative importance of these attributes has not been established quantitatively. Thus a single performance index combining all these attributes is not available. The following hypothesis about the preference hierarchy has been used:

Baby use =	Dry slip + wet slip	absorbency	flow	spreadability
Adult use =	Dry slip + wet slip	absorbency	flow	
	adhesion	spreadability	last	

There are few quantitative, objective laboratory test methods established for measuring these attributes. Product acceptability has normally been measured through expert and consumer subjective opinions against known standards. These are:

- 3 -

<u>Attribute</u>	<u>Test Method</u>
- Dry slip (smoothness, softness, etc.)	Subjective feel against Windsor 66 standard (usually Johnson's Baby Powder)
- Wet slip	Same as above
- Absorbency	Timed water uptake: GATS cc of H ₂ O/gm of powder/unit of time
- Adhesion	Subjective opinion
- Flow	a. Rotating shaker: gm of powder dispensed/unit of time b. Angle of repose: angle in degrees of mound of powder dispensed from funnel
- Spreadability	Subjective feel and observation of coverage against standard
- Respirable Safety	Dusting test using impact meter: mg of powder under 10 microns/meter ³ of air per gm of powder

2. Technical Considerations

The physical mechanisms of actions, rather than the biological, provide the basis for attributes. In general, powders are particles of granular, spherical or platelet shape and can be found naturally or synthesized.

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POWDERS

<u>Material</u>	<u>Shape</u>	<u>Water Affinity</u>
<u>Natural</u>		
Talc	Plates - Granular	Hydrophobic (water & oil wettable)
Clays	Granular	Hydrophilic
Chalks	Granular	Hydrophobic (wetable)
Graphite	Plates	Hydrophobic
<u>Organic</u>		
Starches	Spherical	Hydrophilic
- Corn	■	■
- Potato	■	■
- Rice	■	■
- Tapioca	■	■
- Modified	Plates - spheres	Hydrophilic to hydrophobic
Cellulosics	Fibers	Hydrophilic
<u>Synthetic</u>		
Nylon	Plates - Granular	Hydrophobic to hydrophilic
Polyesters	Plates - Granular	

All particle shapes can provide surfaces which give the dry slip feel. Wet slip occurs when hydrophobic materials exhibit surface wetability, which still allows particles to slide over each other.

Because of the smooth surfaces, adhesion is dependent only on van der WAALS forces at the molecular level between the powder particle and the skin substrate spreading powders on the skin greatly improves adhesion. Because there are relatively weak forces, adhesion when powder is sprinkled on dry skin is low.

Flow and spreadability are affected by the particle shape. Spherical particles have the least surface and contact areas, and so have the lower interparticle attraction. Platelets expose more surface area and offer significantly more contact areas...thus greater interparticle attractions. Thus, flow is generally greater with spherical powders. On the other hand, the ability of platelets to slide over one another helps overcome interparticle attraction. So, when the spreading forces are in the same plane as the platelet direction, spreadability differences between spherical and platelet particles are not as noticeable as flow differences.

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Potential Respirable Hazard is related to chemical composition and particle size.

Any shape particles can be respirable. The key issues are:

- Do the particles remain or are they exhaled? *or trapped or expectorated or swallowed*
- If they remain, are there other exit mechanisms from the body?
(Such as transport through a circulatory system and excretion.)
- If not, does the physical presence a chemical composition induce a physiologic reaction that is negative?
- Do the particles translocate to another site where a different and negative physiologic reaction can take place?

The current body of scientific literature support that cosmetic powders are different from asbestos and silica which have known toxicity.

Absorbency is related to the chemical associates frequently found with the pure talc powders and to surface wettability properties. When talc has small levels of alkaline carbonates, it will also show some absorbtivity. The starches wet and can absorb water. Wettability of all powders can be increased through the use of surfactants.

3. Attribute Limits

Only some of the functional and product attributes use objectively measured values (absorbency, flow, and toxicity [level of respirable dust]). Determining the limits of the other attributes must, at this time, be done qualitatively. The results of numerous consumer tests are summarized:

Dry Slip (Smoothness, softness, lubricity)

None	Consumer Expectation Range			Beyond
			
Corn starch	JBCS Diaperene	JBP	"Super" talc	

Wet Slip

None	Consumer Noticeability			
			
Cornstarch	Talc			

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Absorbency

0	0.35	0.85	1.2	1.7	3.0
V66 Talc JBP	Other Talc Products Diaperene	JBCS	JBCS With ARD	ZEASORB	Shower to Shower P o	cm ³ /gm/5 min (free swell) Cellulose Super Absorbents

Adhesion (Dry Skin)

					Good
Most Powders Similar					

Flow

None	0.16	0.4	0.95	1.38	
	Shower To Shower	Talc JBP	Diaperene	JBCS	Rotating shaker gm/time

Spreadability (Dry Skin)

Poor					Good
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	Other Talc Products	Shower to Shower	JBP JBCS		
Potential Inhalation Hazard <i>of Respirable dust 10 micron and below ESD (equivalent spherical diam)</i>					

0	2	10	Very dusty	mg/m ³	Threshold Limit Value
	Talc JBP		Limit for all nuisance dust in workplace		

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There are trade-offs among all these attributes. For example, as absorbency or adhesion are increased, these wet slip and flow properties are increased. The four key attributes are:

Absorbency
+

Dry Slip + _____ 0 _____ +Adhesion

+
Wet slip

Currently the two major powders - cornstarch and talc - map rather differently.

Cornstarch

Talc

Current consumer knowledge suggest these different products are perceived quite differently but both are accepted cosmetic powders.

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B. MARKET DYNAMICS

Being written

C. TECHNOLOGICAL CHANGE FORECAST

1. Remaining technical potential of current technologies estimates.

P	Dry Slip	P	Wet Slip
	Super talc		J&J talc
Consumer Expectations			Cornstarch
	J&J talc, Cornstarch		

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Other potential additives include cellulose, modified (chemically treated) starches, synthetic powders and super absorbent materials. While some have been shown to improve cornstarch characteristics, labeling and safety concerns have limited our pursuit of the technologies.

Non-Powder Additives

Liquids or semi solids such as petrolatum, mineral oils, and carbowaxes have been applied to talc. Benefits of the addition include improved fragrance retention, reduced respirable particles, reduced dustiness and improved spreadability and adhesion. The addition at meaningful levels causes reduced powder softness and lubricity. U.S. and foreign patents have been issued to J&J covering some of these findings.

3. Technical Potential of Other Unmarketed Technologies

- Biocellulose

D. KEY STRATEGIC ISSUES

1. Consumer Attributes

- Are the attribute mix and level of preference the same for a baby powder vs. an adult powder?
 - Absorbency needs different?
 - Adhesion needs more appreciated with adults?
 - Is the unique wet slip of talc an advertisable benefit for adults?
 - Can quantitative test methods be developed for all high attributes?

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2. Technical Issues

- Can synthetic polymers be made to mimic natural powders? Can particle size and shape be better controlled with a synthetic process? Is this a route to insuring no respirable problem particle sizes? Can synthetics be made wettable?

POWDERS NEXT STEPS

- ✓ 1. Check attribute values for J&J cornstarch and talc and adjust on diagrams, if needed. Determine if any laboratory notebooks can provide numerical values (Worksheet 1).
2. Bring together any data on competitive cornstarches and talcs (Worksheet 1). If any attribute values are significantly different, decide why, based on composition of competitive product. For example, if Vaseline talc is more absorbent than J&J, is the chemical composition of Vaseline talc known? Does it have more natural carbonate associates in it?
3. Institute a literature search and bring together any in-house data or knowledge about the attribute values of other powders, e.g. clays, chalks, cellulose polymers (Worksheet 1).
4. Refine composition, consumer needs, and mechanisms frameworks.
5. List barriers that explain differences between theoretical limits and practical levels (Worksheets 2-4).
6. Analyze market dynamics in terms of changing market positions between types of powders and brands of powders, and implications to product characteristic preferences. For example, if cornstarch has been growing at the expense of talc, what benefit might users be seeking?
7. Review patents of past 5 years in powders. Segment by company, by product, by year. Answer these issues:
 - What are all the alternative technologies?
 - Are companies working across several technologies?
 - Is their work continuous?
 - Do the same names repeat on related patents?
 - Do product or process patents dominate?
 - What benefits are being sought? Are new practical levels of performance being reached? To reach a new level, how much effort was put in?

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8. Identify any other unmarketed technologies, not found in patent estate or J&J BPC active R&D, through other sources.
9. Develop point-of-view on which areas have limiting mechanisms that are too difficult to change or overcome.
10. Develop point-of-view on remaining technical potential of other technologies to reach new levels of performance for various attributes.
11. List all areas in which knowledge is incomplete. Identify actions that could be taken if knowledge was perfect. Rank actions according to likely economic benefits. Develop list of strategic issues that should be pursued.
12. Draw conclusions. Make recommendations as to R&D actions.

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CONCLUSIONS

1. J&J is probably working at the consumer desirable limits of cosmetic powders technology:
 - nearly one hundred years of talc based powder experience has kept us the market leader.
 - vertical integration, through ownership of the Windsor mine in the U.S. and major purchase agreements with 11 other world sources, has enabled us to define cosmetic grade talc.
 - Johnson's Baby Powder is the standard for consumer comparison in the U.S., it is preferred over all other cosmetic powders.
 - cornstarch used in cosmetic powders is a commodity food stuff in the U.S. Natural structural limitations and the desire to avoid chemical modification, preclude direct improvements in the current technology.
2. J&J has limited its exploration of new technologies with several constraints:
 - labeled ingredients must be familiar to consumers and must be perceived as safe for baby.
 - safety concerns have restrained investigation of synthetic powder substitutes.
 - questions and challenges to current product safety have led to defensive protectivism of current technology.
3. J&J must pursue technologies which will provide a proven health benefit for use of powders on babies.
 - Johnson's Baby Powder sales are declining along with the overall cosmetic powders market in a classic mature product curve.
 - health professionals recommend against powder use on infants because potential risk exist and there are no health benefits.
 - while sales of powders for use on baby continue, it is inevitable that a "last straw" safety concern will lead to abandonment of powder use, unless health benefits outweigh the risks.

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4. The choice of which new technologies to pursue cannot be forecasted now because:

- consumer needs are not clearly defined.
- technologies which could provide the desired consumer benefits may not have been defined.

5. It is possible to hypothesize that:

- pursuit of technologies which would create talc based powders of higher interest (than JBP) to adults could be profitable.
- major effort should be expended to prove a health benefit for "cosmetic" dusting powders. Effort should probably be directed at cornstarch technologies since the limits of market penetration and potential benefit have not been approached.
- technologies which control or prevent potential safety hazards must be pursued to stifle the negative recommendations of health professionals. Accomplishments in this area will most likely not, by themselves, alter the declining powders use trend.

EXHIBIT 12

Copy to
Alan/Lisa
(By Noon)

- JOHNSON'S BABY POWDER -

8/5/92

Major Opportunities

1. Continue to fully leverage the diaper rash claim against JBP cornstarch.
- Current household usage on Johnson's Baby Powder Pure Cornstarch has declined from 13% in 1989 to 8% in 1991. Continue to support diaper rash claim in order to rebuild product usage.
2. Investigate Redacted (Redacted Redacted) opportunities to grow the franchise.
- Johnson's Baby Powder has a high usage rate among Redacted (52.0%) and among Redacted (37.6%). Additionally usage indices are high for Redacted and Redacted females for JBP talc (139 and 101 respectively). Redacted females also have a high index (151) against JBP cornstarch. The brand can increase volume in 1993 by targeting these groups.
The brand will institute an adult Redacted media program and potentially launch an adult Redacted print effort.

Major Obstacles

1. The franchise faces weakness on several key skus in factory sales and in consumption.

	<u>YTD % +/- YAG</u>	
	<u>JBP</u>	<u>JBP/CS</u>
9 OZ	-35.6%	-26.4%
14 OZ	-9.7%	+6.3%
24 OZ	-14.8%	-31.2%

- JBP 4 OZ is down -6% in all outlets; Drug distribution down 5 points versus YAG.
- JBP 9 OZ is down -13% due to Food and Drug outlets; Drug distribution down 3 points versus YAG.
- JBP 14 OZ is down -11% due to declines in Food and Drug outlets.
- JBP 24 OZ is up +1%; a -10% decline in Drug has been offset by a +9% gain in Mass; Drug distribution is down 7 points versus YAG.
- JBPCS 9 OZ is down -8% due to declines in Food and Drug

Plaintiff's Exhibit
No.

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- JBPCS 24 OZ is down -7% due to declines in Drug and Mass; Mass distribution is down 9 points.
 - To correct this trend, renewed focus is needed on 9 oz and 24 oz sizes of the franchise. (Focus on building distribution in Drug and making these skus part of 1993 Ring Club.)
2. Negative publicity from the health community on talc (inhalation, dust, negative doctor endorsement, cancer linkage) continues.
 - Investigate the addition of an additive to reduce dust.
 - Encourage the reduction of dust in use by developing advertorial copy and media strategy to promote proper way to powder and diaper a baby.
 3. Little differentiation on JBP talc and cornstarch versus private label.
 - Implement temporary price roll-backs on JBP and JBPCS (using PSP funds) to achieve merchandisable price points and attack private label in the absence of value added news ~~long term~~ (R15, P18)
 - Investigate JBP medicated line extension as news for second half 1993/1994.
 - Evaluate "time release" formula and /or oatmeal as second half 1993 news.
 4. Mennen competitive coupon pressures strong YTD.
 - Participate in broad based infant coupon programs to combat pressure from Mennen (Period 2 FSI).
 5. Talc is adult focussed business in baby focussed line.
 - Longer term, investigate moving brand to a different franchise.
 - Short term, supplement infant plan with periodic adult promotional support
 - Period 5 "Adult" FSI